IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Gil M. Vardi Confirmation No.: 3207 Serial No.: 10/762,562 Examiner: Thomas Sweet

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For: CATHETER WITH ATTACHED FLEXIBLE SIDE SHEATH

Docket No.: 1001.2273105

Customer No.: 28075

REPLY BRIEF

Mail Stop Appeal Brief - Patents Assistant Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

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Lynn Thompson July 31, 2009
Date

The following remarks are submitted after carefully reviewing the Examiner's remarks prepared in the Examiner's Answer mailed June 2, 2009.

Appellants respectfully assert that the Examiner has misunderstood both the Appellants arguments filed in the Appeal Brief on March 10, 2009 and the teachings of Wilson et al. (U.S. Patent No. 6,165,195). Notably, on page 6 of the Examiner's Answer, the Examiner states "Applicant is relying on the 'or' statement to say only one member is viewed during the placement. However, the underline statement lists several members having radiopaque markings (including 55A the lumen of the side sheath), the drawing show radiopaque coil tipped guide wires and contrast medium is inherently used in the vessel to see the vessel." Appellants respectfully assert that this statement does not accurately characterize the spirit of Appellants previous arguments, as well as the teachings of Wilson et al. Appellants respectfully assert that the "or" statement is not relied on to say only one member is viewed during the placement, as suggested by the Examiner, but, instead, the cited passage of Wilson et al., namely column 17, line 64 through column 18, line 14, refers to two different embodiments where each embodiment only discloses a (i.e. one) radiopaque marker on a single lumen. For convenience, the cited

passage is reproduced:

In order to assist in properly aligning both proximal angled stent 10 and mainvessel stent 20 in side-branch vessel 5 and main-vessel 6, respectively, positioning guide wire lumen 39A, on side-branch catheter 31, and guide wire lumen 55A, on main-vessel catheter 50, can be radiopaque, or have a radiopaque marker associated therewith so that they are visible under fluoroscopy. Thus, when advancing side-branch catheter 31 and main-vessel catheter 50, the proper orientation can be more easily determined by viewing the position of positioning guide wire lumen 39A in connection with main-vessel 6 or positioning guide wire lumen 55A in connection with aligning aperture 25 with side-branch vessel 5. Additionally, positioning guide wire 56A for positioning main-vessel stent 20 and positioning guide wire 41A for positioning angled stent 10 are either radiopaque or have radiopaque portions, such as gold markers, to assist in positioning and orienting the catheters and stents during implantation and deployment.

(Emphasis added). As can be clearly seen, this passage refers to aligning both proximal angled stent 10 in the side-branch vessel 5 and the main-vessel stent 20 in the main-vessel. Referring to the drawings for simplicity, some Figures, such as for example, Figures 5 and 7-11, show angled stent 10 and a stent delivery system 30 for a delivery the angled stent 10 to the side-branch vessel 5, whereas other Figures, such as for example, Figures 6 and 12-13, show main-branch stent 20 and a stent delivery system for a delivery the main-branch stent 20 to the main-branch vessel 6. Clearly, the main branch delivery system and the side branch delivery system are two different catheter embodiments. Further, in each catheter embodiment, the cited passage appears to disclose a radiopaque marker associated with the side guide wire lumen, either 55A or 39A, depending on the embodiment. Nothing in this passage appears to disclose multiple radiopaque markers or multiple catheter components having radiopaque markers on a catheter.

While Appellants agree with the Examiner that the cited passage lists several members having radiopaque markers, the radiopaque markers, however, appear to be on corresponding elements in <u>different</u> catheter systems (e.g. guide lumen 39A for the main-branch system and guide wire lumen 55A for the side-branch system). For example, each catheter system appears to only disclose a radiopaque marker on the side branch guide wire lumen. As such, even combining the various embodiments, only the side branch guide wire lumen would appear to include a radiopaque marker. Accordingly, only one radiopaque marker appears to be viewed during fluoroscopy because Wilson et al. appears to only teach a single radiopaque marker on each catheter embodiment.

The Examiner's Answer continues to state "Applicant is suggesting each of the other markers visible under fluoroscopy is ignored during placement (So why include the markings?)". Appellants respectfully assert that nothing in this Reply Brief or the previously filed Appeal Brief suggests "ignoring" markers. Instead, as noted above, there is just simply nothing in the cited passage of Wilson et al. that teaches multiple markers in a single embodiment. To answer the Examiner's question of "so why include the markings", the answer is simply that nothing in Wilson et al. discloses multiple markers on a single embodiment of a stent delivery system. Hence, no markers disclosed by Wilson et al. are ignored, they just are simply not there.

In view of the foregoing, nothing in Wilson et al. appears to teach or suggest "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 1.

For at least the reasons stated above and the reasons submitted in Appellants' Appeal Brief, the rejections of claims 1-7, 9, and 24 under 35 U.S.C. § 103(a) should be overruled.

Respectfully Submitted,

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